510(k) Summary MyLab70 Ultrasound Imaging System Esaote, S.p.A.

JUN 1 - 2005

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR \$807.92(a).

807.92(a)(1)

Submitter Information

Carri Graham, Official Correspondent The Anson Group 7992 Castleway Drive Indianapolis, Indiana 46250

Phone: (317) 849-1916 x103 Facsimile: (317) 577-9070

Contact Person:

Carri Graham

Date:

May 16, 2005

807.92(a)(2)

Trade Name:

(6150) MyLab70 Ultrasound Imaging System

Common Name:

Ultrasound Imaging System

Classification Name(s):

Ultrasonic pulse doppler imaging system 892.1550

Ultrasonic pulsed echo imaging system 892.1560

Classification Number:

90IYN; 90IYO

807.92(a)(3)

Predicate Device(s)

Esaote, S.p.A.	7250 Ultrasound Imaging System	K982444
Esaote, S.p.A.	7250 Ultrasound Imaging System	K994369
Esaote, S.p.A.	7350 Ultrasound Imaging System	K050326
Esaote, S.p.A.	Technos Ultrasound Imaging System	K014168
Esaote, S.p.A.	Technos Ultrasound Imaging System	K023255

510(k) Summary MyLab70 Ultrasound Imaging System Esaote, S.p.A.

807.92 (a)(4)

Device Description

The MyLab 70 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies. Its primary modes of operation are: B-Mode, M-Mode, Doppler and Color Flow Mapping and, on lower frequency probes, Tissue Enhancement Imaging (TEI). The MyLab70 is equipped with a CRT Color Display. The full alphanumeric keyboard allows complete on-screen data entry of patient information and on-screen annotations.

The MyLab70 can drive phased (PA), convex (CA), linear array (LA) and Doppler probes.

The MyLab70 is equipped with a DVD-RW disk drive that can be used for image storage. Data can also be stored directly to a Personal Computer via a LAN port. Optional accessory devices available for the MyLab70 include a S-VHS video recorder and a monochrome or color page printer. The MyLab70 is equipped with an isolation transformer to adequately insulate the system's peripherals.

807.92(a)(5)

Intended Use(s)

Esaote's MyLab70 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Adult Cephalic, Pediatric and Other: Urologic.

807.92(a)(6)

Technological Characteristics

	MyLab 70	Technos	7350 MyLab 50		
	this submission	(K014168 & K023255)	(K050326)		
Electrical Safety	IEC60601-1	IEC60601-1	IEC60601-1		
Ultrasound Safety	Track 3 (Acoustic	Track 3 (Acoustic	Track 3 (Acoustic Output		
	Output Display)	Output Display)	Display)		
Indication for Use					
OB/Fetal	YES	YES	YES		
Abdominal	YES	YES	YES		
Pediatric	YES	YES	YES		
Small organ	YES	YES	YES		
Neonatal Cephalic	YES	YES	YES		
Adult Cephalic	YES	YES	YES		
Cardiac	YES	YES	YES		
Transesophageal	YES	YES	YES		
Transrectal	YES	YES	YES		
Transvaginal	YES	YES	YES		
Peripheral Vascular	YES	YES	YES		
Musculoskeletal	YES	YES	YES		
(conventional & superficial)			125		
Probe Technology					
Phased Array	YES	YES	YES		
Linear Array	YES	YES	YES		
Convex Array	YES	YES	YES		
Doppler Probes	YES	YES	YES		
Bi-Scan	YES	NO	NO		
Modes of operation			NO .		
2D, M-Mode, PW, CW, CFM,	YES	YES	YES		
Amplitude Doppler (PD), TEI		125	1123		
CnTI	YES	YES	No		
TVM	YES	YES	YES		
VPAN	YES	YES	NO		
Imaging Frequencies	1 ÷16 MHz	1.5 ÷16 MHz	2 ÷ 10 MHz		
CFM/Doppler Frequencies	2 ÷12 MHz	2 ÷12 MHz	2 ÷ 8 MHz		
Tissue Velocity Mapping feature	YES	YES	YES		
Biopsy Guidance					
Biopsy Intended Uses	General Purpose,	General Purpose,	General Purpose,		
	Transrectal,	Transrectal,	Transrectal, Transvaginal		
	Transvaginal	Transvaginal			
Display type	CRT	CRT	CRT		
Display Standard	SVGA	SVGA	SVGA		
Digital Archival Capabilities	YES	YES	YES		

	MyLab 70	Technos	7350 MyLab 50
	this submission	(K014168 & K023255)	(K050326)
DICOM Classes:	Media Storage,	Media Storage, Storage	Media Storage, Storage
	Storage SCU	SCU	SCU
VCR / Page Printer	YES	YES	YES
M&A Capabilities	Cardiac, Vascular, OB and general purpose measurements	Cardiac, Vascular, OB and general purpose measurements	Cardiac, Vascular, OB and general purpose measurements
Weight	110 kg	140 kg	90 kg
Dimensions	60(w) x 160(h) x	60(w) x 160(h) x	60(w) x 155(h) x 90(d)
	90(d) cm	105(d) cm	cm



JUN 1 - 2005

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Esaote, S.p.A. % Ms. Carri Graham Consultant The Anson Group 7992 Castleway Drive INDIANAPOLIS IN 46250

Re: K051308

Trade Name: Model 6150 (MyLab70) Ultrasound Imaging System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Number: 21 CFR 892.1560

Regulatory Name: Ultrasonic pulsed echo imaging system

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: May 16, 2005 Received: May 19, 2005

Dear Ms. Graham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Model 6150 (MyLab70) Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number

EC123	PA230
LA424	TEE022
LA522	TRT23
<u>LA523</u>	<u>2CW</u>
<u>LA532</u>	<u>5CW</u>
<u>PA121</u>	BS230
<u>PA122</u>	PA023

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled,

"Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

Mod. 6150

Clinical Application	Mode of Operation											
	А	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)		
Ophthalmic									· · ·			
Fetal		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)		
Abdominal	<u> </u>	N	N	N_	N	N	N		N (see Note 1)	N (sec Note 2)		
Intraoperative (specify) Intraoperative Neurological										1.000 21		
Pediatric		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)		
Small Organ (specify)		N	N	N	N	N	N		N (sec Note 1)	N (see Note 2)		
Neonatal Cephalic		N	N	N	N	N	N		N (sec Note 1)	N (see Note 2)		
Adult Cephalic		N_	N	N	N	N	N		N (see Note 1)	N (see Note 2)		
Cardiac	<u> </u>	N	N	N	N	_ N	N		N (see Note 1)	N (see Note 2)		
Transesophageal		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)		
Transrectal	ļ	N	N_	N		N	N		N (see Note 1)	N (see Note 2)		
Transvaginal		N	N	N		N	N		N (see Note 1)	N (see Note 2)		
Transurethral												
Intravascular												
Peripheral Vascular		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)		
Laparoscopic Musculo-skeletal										- ·		
Conventional Musculo-skeletal		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)		
Musculo-skeletal Superficial		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)		
Other (Urological)		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)		

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Small Organs (thyroid, testicles, penis and breast);
Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode

Bi-Scan

Kate /	U.S
(Division Sign-Off)	
Division of Reproductive, and Radiological Devices	Abdominal,
510(k) Number	KO51308

Prescription Use_____

CA123

	Mode of Operation											
Clinical Application	A	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)		
Ophthalmic												
Fetal												
Abdominal		N	N	N		N	N		N (see Note 1)	N (see Note 2)		
Intraoperative (specify) Intraoperative Neurological												
Pediatric		N	N	N		N	N		N (see Note 1)	N (see Note 2)		
Small Organ (specify)		N	N	N		N	N		N (see Note 1)	N (see Note 2)		
Neonatal Cephalic		N	N	N		N	N		N (see Note 1)	N (sec Note 2)		
Adult Cephalic												
Cardiac		N	N	N		N	N		N (see Note 1)	N (see Note 2)		
Transesophageal												
Transrectal												
Transvaginal												
Transurethral			<u> </u>									
Intravascular									-			
Peripheral Vascular		N	N	N		N	N		N (sec Note 1)	N (see Note 2)		
Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial												

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Small Organs (thyroid, testicles, penis and breast);
Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+ CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode

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(Division Sign-Off)	7
Division of Reproductive	, Abdominal,
and Radiological Devices 510(k) Number	K05/308

Prescription Use_

	Mode of Operation									
Clinical Application	٨	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic								ļ		
Fetal		N	N	N		l _N	N		N (see Note 1)	N (see Note 2)
recai		 ``			<u> </u>				N (see	N (sec
Abdominal	 	N	N	N	-	N	N	-	Note 1)	Note 2)
Intraoperative (specify)	ļ				ļ					
Intraoperative Neurological						<u> </u>			N (N (see
Pediatric	<u> </u>	N	N	N	ļ	N	N _		N (sec Note 1)	Note 2)
Small Organ (specify)	<u> </u>	 			<u> </u>					<u> </u>
Neonatal Cephalic	↓	<u> </u>		ļ <u> </u>	<u> </u>	· · · · · · · · · · · · · · · · · · ·				<u> </u>
Adult Cephalic			ļ	<u> </u>	ļ		<u> </u>	ļ		 -
Cardiac	.	ļ	ļ	<u> </u>	ļ		ļ	1		
Transesophageal	ļ	<u> </u>		<u> </u>	<u> </u>	 		-	<u> </u>	-
Transrectal			ļ	ļ <u> </u>	ļ			ļ		
Transvaginal	ļ	<u> </u>			<u> </u>	<u> </u>	-	-	1	
Transurethral	<u> </u>	.	<u> </u>	-	<u> </u>	<u> </u>	1	 		<u> </u>
Intravascular			ļ		ļ		<u> </u>	ļ	1	 -
Peripheral Vascular	<u> </u>	N	N	N	<u> </u>	N	N _		N (see Note 1)	N (see Note 2
Laparoscopic		1		.	ļ		1			<u> </u>
Muscolo-skeletal Conventional										
Muscolo-skeletal	1		 	1	1					1
Superficial Other (Urological)	+	N	N	N	1	l N	N		N (see Note 1)	N (see

N= new indication; P= previously cleared by FDA; E= added under Appendix E

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(Division Sign-Off)	
Division of Reproductive, Abdominal,	
and Radiological Devices	
510(k) Number <u>K03/308</u>	

Prescription Use____

Note (1): Combinations: any combination of the following modes: B+M+PW +CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode

CA430

	Mode of Operation										
Clinical Application	A	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic					ļ				N (see	N (see	
Fetal		N	N	N		N	N		Note 1)	Note 2)	
Abdominal		N	N	N		N	N_		N (see Note 1)	N (see Note 2)	
Intraoperative (specify)					ļ <u>-</u>			<u> </u>			
Intraoperative Neurological	<u> </u>	ļ	ļ <u>. </u>	ļ <u>-</u>	<u> </u>	<u> </u>		<u> </u>	ļ	<u> </u>	
Pediatric	ļ	 		ļ	<u> </u>	ļ	<u></u>	<u> </u>	ļ <u>-</u>	-	
Small Organ (specify)	-				ļ		<u> </u>	<u> </u>		<u> </u>	
Neonatal Cephalic	<u> </u>	<u> </u>	<u> </u>	<u> </u>	ļ		<u> </u>				
Adult Cephalic	<u> </u>			ļ	 		<u> </u>	ļ	1		
Cardiac	ļ	<u> </u>		<u> </u>	-	-	<u> </u>	 	+	-	
Transesophageal	<u> </u>	<u> </u>	<u> </u>	ļ	<u> </u>	<u> </u>	<u> </u>	 			
Transrectal		<u> </u>	ļ	<u> </u>	<u> </u>	<u> </u>	<u> </u>	_	 	-	
Transvaginal		↓	ļ	<u> </u>	<u> </u>		<u> </u>	· 	·	ļ	
Transurethral			<u> </u>	1	<u> </u>	<u> </u>	ļ			 	
Intravascular	<u> </u>	<u> </u>		<u> </u>					N (see	N (see	
Peripheral Vascular		N	N	N	_	N	N		N (see Note 1)	Note 2	
Laparoscopic Muscolo-skeletal Conventional											
Muscolo-skeletal Superficial											
Other		<u> </u>		<u> </u>			<u> </u>			<u> </u>	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

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(Division Sign-Off) Division of Reproductive, A and Radiological Devices 510(k) Number	Abdominal, <u>(057308</u>

Prescription Use_____

Note (1): Combinations: any combination of the following modes: B+M+PW +CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode

CA621

				 	-	Mode of C	peration			
Clinical Application	Α	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N	Í	N (see Note 1)	N (see Note 2)
Abdominal		N	N	N		N	N		N (see Note 1)	N (sec Note 2)
Intraoperative (specify) Intraoperative Neurological										
Pediatric			ļ		ļ					
Small Organ (specify)	<u> </u>	ļ						<u> </u>		
Neonatal Cephalic										
Adult Cephalic	ļ	,			ļ					
Cardiac	<u> </u>	ļ								
Transesophageal						ļ				
Transrectal		<u> </u>								
Transvaginal										
Transurethrai										
Intravascular										
Peripheral Vascular		И	N	N		N	N		N (see Note 1)	N (see Note 2)
Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial										
Other (Urological)		N	N	N		N	N		N (see Note 1)	N (see Note 2)

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Ra-a Phells	
Division Sign-Off)	
Division of Reproductive, Abdominal, (
and Radiological Devices	
510(k) Number <u>K00/308</u>	

Note (1): Combinations: any combination of the following modes: B+M+PW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode

EC123

						Mode of O	peration			
Clinical Application	A	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N_		N (see Note 1)	N (see Note 2)
Abdominal										ļ
Intraoperative (specify)										
Intraoperative Neurological									<u> </u>	
Pediatric				<u> </u>						
Small Organ (specify)		<u> </u>								
Neonatal Cephalic	ļ		<u> </u>	ļ		ļ				
Adult Cephalic	<u> </u>	ļ		<u> </u>		<u> </u>				ļ
Cardiac	ļ	ļ — —		ļ				-		
Transesophageal	ļ	ļ		<u> </u>	ļ	ļ		 	N (see	N (sec
Transrectal		N	N	N		N	N		Note 1) N (see	Note 2) N (see
Transvaginal	<u> </u>	N	N	N		N	N	<u> </u>	Note 1)	Note 2)
Transurethral	<u> </u>		ļ	<u> </u>		<u> </u>		<u> </u>		<u> </u>
Intravascular	 	<u> </u>			ļ		<u> </u>		<u> </u>	
Peripheral Vascular	ļ	ļ		ļ				-		
Laparoscopic Musculo-skeletal Conventional										
Musculo-skeletal Superficial										<u> </u>
Other (Urological)		N	N	N		N	N		N (see Note 1)	N (see Note 2)

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Note (1): Combinations: any combination of the following modes: B+M+PW +CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode

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Division Sign-Off)	
Division of Reproductiv	re, Abdominal,
and Radiological Devic	es UNGIANS
F 100kt Number	100100

						Mode of C	peration			-
Clinical Application	۸	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic									,	
Fetal								ļ		
Abdominal										
Intraoperative (specify)				ļ			ļ			
Intraoperative Neurological	ļ									
Pediatric		N	N	N		N	N		N (see Note 1)	
Small Organ (specify)		N	N	N		N	N		N (see Note 1)	
Neonatal Cephalic	<u> </u>	ļ			<u> </u>				· .	
Adult Cephalic	<u> </u>		ļ	<u> </u>		<u> </u>				
Cardiac	ļ	ļ		<u> </u>						
Transesophageal	ļ			ļ		<u> </u>			ļ <u>.</u>	
Transrectal				ļ		<u> </u>				ļ
Transvaginal	<u> </u>			<u> </u>						
Transurethral	ļ					ļ		ļ 		
Intravascular	<u> </u>				ļ	ļ				
Peripheral Vascular		N	N	N		N	N		N (see Note 1)	ļ
Laparoscopic		ļ <u>.</u>	l							
Musculo-skeletal Conventional		N	N	N		N	N		N (see Note 1)	
Musculo-skeletal Superficial		N	N	N		N	N		N (see Note 1)	
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Small Organs (thyroid, testicles, penis and breast);
Peripheral Vascular to include Vein Mapping & Scieroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW +CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number ___

Diescription Use____

	Mode of Operation											
Clinical Application	A	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)		
Ophthalmic	<u> </u>		i		<u> </u>			<u>-</u>				
Fetal	<u> </u>				 	ļ	·					
Abdominal	ļ			<u> </u>	ļ	ļ		ļ				
Intraoperative (specify) Intraoperative Neurological									N (see			
Pediatric		N	N	N		N	N		Note 1)			
Small Organ (specify)		N	N_	N		N_	N	<u> </u>	N (see Note 1)			
Neonatal Cephalic				<u> </u>	ļ	<u> </u>			<u> </u>	<u> </u>		
Adult Cephalic	<u> </u>	ļ		ļ		<u> </u>	<u> </u>		<u> </u>			
Cardiac	<u> </u>	<u> </u>	<u> </u>	 	_	ļ		 	 	ļ		
Transesophageal	<u> </u>	ļ	<u> </u>		<u> </u>				ļ			
Transrectal	ļ	<u> </u>	<u> </u>		_	<u> </u>		<u>.</u>	<u> </u>			
Transvaginal		<u> </u>		ļ		ļ	<u> </u>	<u> </u>				
Transurethral		<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>		ļ				
Intravascular		<u> </u>	<u> </u>	ļ <u> </u>				<u> </u>				
Peripheral Vascular		N	N	N		N	N _		N (see Note 1)	1		
Laparoscopic Musculo-skeletal Conventional	_	N	N	N		N	N		N (see Note 1)			
Musculo-skeletal Superficial		N	N	N		N	N		N (see Note 1)			
Other						, <u></u>						

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
<u>Small Organs (thyroid, testicles, penis and breast);</u>

Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

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	Mode of Operation												
Clinical Application	A	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)			
Ophthalmic	<u> </u>												
Fetal	ļ <u> </u>								<u> </u>				
Abdominal	<u> </u>												
Intraoperative (specify) Intraoperative Neurological			1										
Pediatric		N	N	N		N	N	İ	N (see Note 1)	N (see Note 2)			
Small Organ (specify)		N	N	N		N	N N		N (see Note 1)	N (see Note 2)			
Neonatal Cephalic	ļ			<u> </u>	ļ			ļ					
Adult Cephalic	<u> </u>												
Cardiac						<u> </u>		<u> </u>					
Transesophageal													
Transrectal	<u> </u>				<u> </u>			1					
Transvaginal		<u> </u>	ļ					<u> </u>					
Transurethral								ļ					
Intravascular		ļ											
Peripheral Vascular		N	N	N		N	N		N (see Note 1)	N (see Note 2)			
Laparoscopic Musculo-skeletal Conventional		N	N	N		N	N		N (see Note 1)	N (see Note 2)			
Musculo-skeletal Superficial		N	N	N		N	N		N (see Note 1)	N (see Note 2)			
Other													

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Small Organs (thyroid, testicles, penis and breast);
Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode

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						Mode of C	peration			
Clinical Application	A	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	-									
Fetal	ļ				ļ <u> </u>					
Abdominal				ļ	ļ <u>.</u>				ļ	
Intraoperative (specify) Intraoperative Neurological										
Pediatric		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Small Organ (specify)		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Neonatal Cephalic				ļ						
Adult Cephalic	ļ	<u> </u>		<u> </u>	ļ <u> </u>			<u> </u>		
Cardiac		<u> </u>			<u> </u>		<u> </u>	<u> </u>		<u> </u>
Transesophageal	<u> </u>	<u> </u>	ļ		ļ					<u> </u>
Transrectal		<u> </u>								<u> </u>
Transvaginal	<u> </u>							<u> </u>		
Transurethral		1						<u> </u>		
Intravascular		<u> </u>	1		<u> </u>				ļ	
Peripheral Vascular		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Laparoscopic Musculo-skeletal Conventional Musculo-skeletal										
Superficial			-		 	 	-	1		
Other					<u></u>					<u> </u>

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Small Organs (thyroid, testicles, penis and breast);
Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode

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					Mode of O	peration			
A	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
	N	N	N	<u> </u>	N	N		N (see Note 1)	N (sec Note 2)
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		<u> </u>							
ļ				ļ			ļ		
	N	N	N	ļ	N	N		N (see Note 1)	N (sec Note 2)
			ļ						
	ļ			ļ			ļ		
ļ				ļ			<u> </u>	ļ	
			1						ļ
			<u> </u>				ļ	ļ	
				ļ	ļ		ļ	ļ	
	A	N	N N	N N N	N N N N	A B M PWD CWD COlor Doppler (CFM)	A B M PWD (PW) Doppler (PD) N N N N N N N N N N N N N N N N N N	A B M PWD CWD COlor Doppler (CFM) PDoppler (PD) Planging N N N N N N N N N N N N N N N N N N N	A B M PWD (PW) CWD CONDOPPLET (CFM) Color Doppler (PD) Planging (specify) N N N N N N N N N N N N N N N N N N N

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Note (1): Combinations: any combination of the following modes: B+M+PW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode

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	Mode of Operation												
Clinical Application	A	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)			
Ophthalmic	<u> </u>							'					
Fetal													
Abdominal													
Intraoperative (specify) Intraoperative Neurological													
Pediatric		N	N	N	N	N	N		N (see Note 1)				
Small Organ (specify)		ļ											
Neonatal Cephalic		N	N	N	N	N	N		N (see Note 1)				
Adult Cephalic													
Cardiac	ļ	N	N	N	N	N	N		N (see Note 1)				
Transesophageal	<u> </u>	<u> </u>			<u> </u>								
Transrectal					<u> </u>					<u></u>			
Transvaginal				<u> </u>									
Transurethral			ļ		<u> </u>								
Intravascular		<u> </u>				İ							
Peripheral Vascular		N	N	N	N	N	N		N (see Note 1)				
Laparoscopic Muscolo-skeletal Conventional Muscolo-skeletal Superficial													
Other													

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

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						Mode of C	peration			
Clinical Application	A	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)
Intraoperative (specify) Intraoperative Neurological										
Pediatric		ļ								
Small Organ (specify)	ļ	ļ			<u> </u>			ļ		
Neonatal Cephalic				<u> </u>						
Adult Cephalic	<u> </u>	N	N	N	N	N	N		N (see Note 1)	N (see Note 2)
Cardiac		N	N	N	N	N	N _		N (see Note 1)	N (see Note 2)
Transesophageal		<u> </u>	ļ		ļ					<u> </u>
Transrectal	ļ	<u> </u>	<u> </u>	<u> </u>				<u> </u>		ļ <u>.</u>
Transvaginal	<u> </u>	<u> </u>	<u> </u>	1		ļ <u>.</u>		ļ		
Transurethral		1						ļ		<u> </u>
Intravascular	<u> </u>		1		<u> </u>		1	<u> </u>		
Peripheral Vascular	<u> </u>	<u> </u>	ļ		<u> </u>	1		ļ		<u> </u>
Laparoscopic Muscolo-skeletal Conventional Muscolo-skeletal Superficial										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number __

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode

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Mode of Operation											
A	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)		
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		<u> </u>						<u></u>	<u> </u>		
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ļ <u>.</u>	ļ	<u> </u>	ļ								
	<u> </u>				ļ		ļ	N (gae			
	N	N	N	N	N	N	ļ	Note 1)			
ļ <u>.</u>	N	N	N	N	N	N		Note 1)			
<u> </u>	<u> </u>				<u> </u>						
	<u> </u>	ļ	<u> </u>	ļ. <u></u>	ļ	ļ <u>.</u>	ļ				
<u> </u>	1			ļ	<u> </u>	<u> </u>		<u> </u>			
ļ			ļ	<u> </u>	<u> </u>	<u> </u>			<u> </u>		
			ļ		ļ						
	A	N	N N	A B M (PW)	A B M (PW) (CW)	A B M PWD CWD COlor Doppler (CFM)	A B M PWD CWD Color Doppler (CFM) Amplitude Doppler (PD)	A B M PWD CWD CPW CPW CPW CPW Poppler (PD) Color Velocity Imaging N N N N N N N N	A B M PWD (CW) Color Doppler (CFM) Color (PD) Color (specify) N N N N N N N N N N N N (see Note 1) N (see		

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

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	Mode of Operation										
Clinical Application	۸	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic											
Fetal											
Abdominal	<u> </u>										
Intraoperative (specify)	<u></u>	<u> </u>									
Intraoperative Neurological											
Pediatric											
Small Organ (specify)	ļ										
Neonatal Cephalic	<u> </u>		<u> </u>		ļ					ļ	
Adult Cephalic	ļ						!				
Cardiac	ļ			ļ	<u> </u>	 					
Transesophageal		ļ			<u> </u>			ļ	N//		
Transrectal		N	N	N		N	N N		N (see Note 1)		
Transvaginal		ļ			<u> </u>		<u> </u>				
Transurethral	ļ				ļ		ļ				
Intravascular	<u> </u>			<u> </u>	ļ .					<u> </u>	
Peripheral Vascular	-			<u> </u>							
Laparoscopic	<u> </u>			<u> </u>				<u></u>			
Muscolo-skeletal			1								
Conventional	₩	ļ	ļ	1	1	ļ	ļ	 	<u> </u>	 	
Muscolo-skeletal Superficial			1]	
Other (Urological)		N	N	N		N	N		N (see Note 1)	1	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Note (1): Combinations: any combination of the following modes: B+M+PW +CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

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	Mode of Operation											
Clinical Application	A	В	М	PWD (PW)	(CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)		
Ophthalmic												
Fetal	<u> </u>											
Abdominal												
Intraoperative (specify) Intraoperative Neurological												
Pediatric				ļ		ļ						
Small Organ (specify)												
Neonatal Cephalic												
Adult Cephalic	ļ			ļ		ļ						
Cardiac				<u> </u>	N							
Transesophageal	ļ		<u> </u>	ļ								
Transrectal	<u> </u>	ļ		<u> </u>		ļ						
Transvaginal	<u> </u>	<u> </u>				<u> </u>			ļ			
Transurethral						<u> </u>						
Intravascular					<u> </u>	ļ				<u> </u>		
Peripheral Vascular									_			
Laparoscopic Muscolo-skeletal Conventional Muscolo-skeletal Superficial												
Other												

N= new indication; P= previously cleared by FDA; E= added under Appendix E

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and Radiological Devices	NOS2888
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Mode of Operation											
A	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)		
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<u> </u>			ļ	N							
	A	A B	A B M		A B M (PW) (CW)	A B M PWD (CW) Doppler (CFM)	A B M (PW) (CW) Doppler (PD) Doppler (PD)	A B M (PW) (CW) Doppler (PD) Velocity Imaging	A B M (PW) (CW) Doppler (CFM) Doppler (PD) Imaging (specify)		

N= new indication; P= previously cleared by FDA; E= added under Appendix E

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	Mode of Operation										
Clinical Application	A	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic											
Fetal		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)	
Abdominal		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)	
Intraoperative (specify) Intraoperative Neurological											
Pediatric											
Small Organ (specify)	<u> </u>			ļ	ļ	ļ					
Neonatal Cephalic											
Adult Cephalic	<u> </u>										
Cardiac	ļ			<u> </u>				ļ			
Transesophageal	<u> </u>		ļ	ļ	ļ			<u> </u>			
Transrectal					ļ						
Transvaginal		<u> </u>									
Transurethral				<u> </u>	ļ 						
Intravascular		ļ		<u> </u>	ļ	<u> </u>	ļ	<u> </u>		ļ	
Peripheral Vascular				ļ	ļ			ļ			
Laparoscopic Musculo-skeletal Conventional Musculo-skeletal Superficial											
Other											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode Bi-Scan

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	Mode of Operation										
Clinical Application	A	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (specify) Intraoperative Neurological											
Pediatric		N	N	N	N	N	N		N (see Note 1)		
Small Organ (specify)					<u> </u>						
Neonatal Cephalic		N	N	N	N	N	N		N (see Note 1)		
Adult Cephalic	<u> </u>										
Cardiac		N	N_	_N	N	N	N		N (see Note 1)		
Transesophageal											
Transrectal	<u> </u>										
Transvaginal											
Transurethral	ļ										
Intravascular											
Peripheral Vascular		N	N	N	N	N	N		N (see Note 1)		
Laparoscopic Muscolo-skeletal Conventional Muscolo-skeletal Superficial											
Other N= new indication: P= new											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

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